FEB 2 8 2007

Vascular SOLUTIONS

510(k) Summary

510(k) Number: K063871

Date Prepared

Submitter Information

Submitter's Name/ Address:	Vascular Solutions, Inc. 6464 Sycamore Court Minneapolis, MN 55369
Establishment Registration	2134812
Contact Person:	Alyssa Malinski

Device Information

Trade Name: Vascular Solutions D-Stat Handle™
Common Name: Topical Hemostat/Vascular Clamp
Classification Name: Vascular Clamp
Product Code: DXC
Regulation: 21 CFR 870.5150

Predicate Device(s)

D-Stat Clamp Accessory (K050146)
FemoStop (K915280)
EZ Hold (K973132)

Device Description

Each D-Stat Handle consists of the following components:

- Stainless Steel handle and shaft with a configured press fit attachment for the D-Stat Dry Clamp accessory.

Intended Use/Indications for Use
The D-Stat Handle is indicated for use with the D-Stat Clamp accessory to assist in the control of bleeding following catheterization or cannulation procedures.

Summary of Non-Clinical Testing
To test the performance requirements of the D-Stat Handle, the non-clinical testing included; ensuring that the device is reusable by being able to disconnect and reattach to 10 different clamp bases. It was weight tested, verifying that the device weighs less than 1.5 lbs. The D-Stat Clamp base was tested to confirm that it will stay attached to the D-Stat Handle after vertical shaking for 2 seconds. Comparable to current commercial hand held compression devices the D-Stat Handle was tested to ensure that it delivers even surface pressure.

Summary of Clinical Testing
No clinical evaluations of this product for this use have been conducted.

Statement of Equivalence
The D-Stat Handle and D-Stat Clamp accessory are substantially equivalent to the FemoStop and EZ Hold.

Conclusion
The D-Stat Handle is suitable for the intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Vascular Solutions, Inc.
Ms. Alyssa Malinski
Regulatory Affairs Assistant
6464 Sycamore Court
Minneapolis, MN 55369

Re: K063871
Trade/Device Name: D-Stat Handle, model number 8500-053
Regulation Number: 21 CFR 870.4450
Regulation Name: Vascular clamp
Regulatory Class: Class II
Product Code: DXC
Dated: December 27, 2006
Received: December 29, 2006

Dear Ms. Malinski:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donna R. Vochmer

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K063871

Device Name: D-Stat Handle
D-Stat Clamp accessory

Indications for Use:

The D-Stat Handle is indicated for use with the D-Stat Clamp accessory to assist in the control of bleeding following catheterization or cannulation procedures.

The D-Stat Clamp accessory is indicated for use with the CompressAR Universal System (Advanced Vascular Dynamics) and the Femoral Artery Vascular Clamp (Pressure Products) compression devices or as a stand-alone device to assist in the control of bleeding following catheterization or cannulation procedures. Following achieving hemostasis the D-Stat Dry Bandage may be detached from the D-Stat Clamp accessory and left in place for up to 24 hours and is indicated for the control of surface bleeding from vascular access sites and percutaneous catheters or tubes.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vo Jones

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510(k) Number K063871